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INTERNATIONAL PRELIMINARY EXAMINATION REPORT (PCT Article 36 and Rule 70)

Applicant's or agent's file reference 70059	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/EP 03/08197	International filing date (day/month/year) 25.07.2003	Priority date (day/month/year) 26.07.2002
International Patent Classification (IPC) or both national classification and IPC C12N15/82		
Applicant SYNGENTA PARTICIPATIONS AG		



1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 8 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

 These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 15.12.2003	Date of completion of this report 04.11.2004
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I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-25 as originally filed

Sequence listings part of the description, Pages

1 as originally filed

Claims, Numbers

1-45 as originally filed

Claims, Pages

1-6 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☒ contained in the international application in written form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
☒ claims Nos. 1-12,14,15,17-26 (partially);31,32 (completely)

because:

- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

- ☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 1-12,14,15,17-26 (partially) are so unclear that no meaningful opinion could be formed (*specify*):

see separate sheet

- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

- ☒ no international search report has been established for the said claims Nos. 1-12,14,15,17-26 (partially); 31,32 (completely)

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

- ☐ the written form has not been furnished or does not comply with the Standard.
☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-12*,13,14*,15*,16,17-26*,27-30,34-45 (see item III)
	No: Claims	33
Inventive step (IS)	Yes: Claims	1-12*,13,14*,15*,16,17-26*,27-30,34-36,38-45 (see item III)
	No: Claims	33,37
Industrial applicability (IA)	Yes: Claims	13,16,27-30,33-45
	No: Claims	-

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2. Citations and explanations

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

As outlined in the International Search Report (ISR), the search for claims 1-12, 14, 15 and 17-26 has been restricted to subject-matter which appeared to be detailed in the description (see ISR, PCT/ISA form 210).

As a consequence, the present International Preliminary Examination Report only relates to the searched subject-matter of those claims.

Claims 31 and 32 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT, i.e. to essentially biological processes.

Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

- D1: CHIANG M S ET AL: "TRANSFER OF RESISTANCE TO RACE 2 OF PLASMIDIOPHORA-BRASSICAE FROM BRASSICA-NAPUS TO CABBAGE BRASSICA-OLERACEA-SSP-CAPITATA 5. THE INHERITANCE OF RESISTANCE" EUPHYTICA, vol. 32, no. 2, 1983, pages 479-484, XP008025438 ISSN: 0014-2336
- D2: WO 00/55340 A (PIONEER HI-BRED INTERNATIONAL, INC.) 21 September 2000 (2000-09-21)

1. It should be noted that the document indicated in the search report as "PX" document has not been taken into consideration for the evaluation of novelty and inventive step, because the priority document of the present application has been **assumed** to be valid and the validity of priorities claimed by documents cited in the International Search Report will not be examined at the present stage (see also official Journal EPO, 11/2001, page 539-542, especially item 13).

2. It is pointed out that the present International Preliminary Examination Report concerning novelty, inventive step and industrial applicability only refers to subject-matter for which an International Search Report has been established.

3. The present application relates to *B. oleracea* plants resistant to clubroot disease, wherein the resistance is monogenic and dominant. Further, methods for producing clubroot resistant *B. oleracea* plants by transferring said resistance from *B. rapa* to *B. oleracea* and to DNA fragments amplified from a Brassica genome by use of a defined primer are claimed.

4. Clarity (Art. 6, PCT)

Article 6, PCT requires that the claims shall **define** the matter for which protection is sought. These claims shall be **clear** and **concise**. Further, Rule 6.3(a) requires that the definition of the matter for which protection is sought shall be in terms of **the technical features** of the invention.

These technical features can then be compared to the prior art to establish whether the claimed subject-matter is novel and inventive.

Present claims 13, 16 and 33-45, do not fulfill the requirements of clarity and conciseness for the following reasons:

4.1 Claims 13 and 16 refer to clubroot resistant *B. oleracea* plants, characterised by a certain segregation pattern, when crossed with a defined "tester" plant. Although said claims might be regarded as "clear" as far as the different steps of crossing, the crossing partner and the desired result of the crossing are concerned, said claims do not define the exact **technical feature** that allow the plant to display a clubroot resistant phenotype, hence present claim 13 and 16 are not clear in the sense of Art. 6, PCT.

4.2 Subject-matter of claims 33 to 35 is not clearly defined insofar as the terms "approximately 400 bp" and "approximately 640 bp" are concerned.
The same objection refers to claims 37 and 38.

4.3 Subject-matter of claims 42-45 do not fulfill the requirement of Art. 6, PCT for the following reasons:

Claim 42 is unclear insofar as

- i) the term "less resistant" is mentioned twice without a reference (less resistance than what?), and
- ii) "obtaining a *B. oleracea* plant comprising a monogenic and dominant resistance to clubroot" is a desideratum, i.e. part b) of claim 42 attempts to define the subject-matter for which protection is thought in terms of a result to be achieved, instead of mentioning **how** the effect is to be achieved, and
- iii) the DNA fragment characterising the plants which are being selected in step c) is not clearly defined (i.e. the length of the DNA fragment, the sequence of the DNA fragment and the conditions under which the primers can generate such a DNA fragment are not defined).

The objection in item (i) also applies to claim 43.

The objections in items (ii) and (iii) also apply to claim 44 and 45.

5. Novelty and inventive step (Art. 33(3)(3), PCT)

5.1 It is pointed out that the remarks relating to novelty and inventive step only have provisional character, since the objections regarding clarity of the present claims are so substantial that a meaningful comparison of the subject-matter for which protection is sought with the prior art cannot be established.

5.2 D1 refers to the transfer of resistance to clubroot (race 2) from *Brassica napus* to *B. oleracea ssp. capitata* by breeding. The clubroot resistance is described as being controlled by a single dominant gene (i.e. monogenic) (p. 482, lines 2-4) and resistant plants are presented in Table 1 left column.
In view of D1, claims referring to clubroot resistant *B. oleracea* plants, wherein the resistance is monogenic and dominant, lack novelty as required by Art. 33(2); PCT.

5.3 D2 relates to transgenic plants, *inter alia* Brassica sp., which display an enhanced disease resistance due to the overexpression of 6-methylsalicylic acid synthase (Examples 4-8). One of the preferred 6-methylsalicylic acid synthase nucleic acid sequences (SEQ ID NO:3) comprises the primer O20 (SEQ ID NO:1) of the present application. Since D2 discloses a DNA that comprises the primer O20 and

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which confers disease resistance, subject-matter of claim 33 is not novel and the use of such a DNA as claimed in claim 37 is not inventive.